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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,596	09/25/2003	David Schmidt	052775-0311431	1315
909	7590	08/19/2008		
PILLSBURY WINTHROP SHAW PITTMAN, LLP			EXAMINER	
P.O. BOX 10500				GHALI, ISIS A D
MCLEAN, VA 22102			ART UNIT	PAPER NUMBER
			1611	
			MAIL DATE	DELIVERY MODE
			08/19/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/669,596	SCHMIDT, DAVID
	<b>Examiner</b>	<b>Art Unit</b>
	Isis A. Ghali	1611

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 19 May 2008.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1,3,5,6,10,11,14,16,18,20,22,24,26,34,36,38,42,58 and 59 is/are pending in the application.  
 4a) Of the above claim(s) 36 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) \_\_\_\_\_ is/are rejected.  
 7) Claim(s) 1,3,5,6,10,11,14,16,18,20,22,24,26,34,3, 42, 58, 59 is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date _____.	6) <input type="checkbox"/> Other: _____

## **DETAILED ACTION**

The receipt is acknowledged of applicant's amendment and request for RCE, both filed 05/19/2008.

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/19/2008 has been entered.

Claims 2, 4, 7-9, 12, 13, 15, 17, 19, 21, 23, 25, 27-33, 35, 37, 39-41, 43-57 have been canceled.

Claims 58 and 59 are currently added.

Claims 1, 3, 5, 6, 10, 11, 14, 16, 18, 20, 22, 24, 26, 34, 36, 38, 42, 58 and 59 are pending.

Claim 36 has been withdrawn from further consideration as being drawn to nonelected species with traverse in the reply filed on 02/28/2007.

Claims 1, 3, 5, 6, 10, 11, 14, 16, 18, 20, 22, 24, 26, 34, 38, 42, 58 and 59 are included in the prosecution.

***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 3, 5, 6, 10, 11, 14, 16, 18, 20, 22, 24, 38, 42, 58 and 59 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,475,514 ('514).

US '514 discloses transdermal patches for administration of nutrient supplement to a subject wherein the patch comprises amino acids (abstract; col.2, lines 47-51, 65-67). The amino acids included hydroxyproline that is claimed by applicant by claim 6 as left-handed molecule, further including alanine, valine, phenylalanine, etc. (col.6, lines 65-67; col.7, lines 1-2, 60-67). The patch further includes L-carnitine (col.8, line 8). The patch comprises backing layer, which reads on the claimed substrate, made of polyester fabric (col.9, lines 5-6; col.11, lines 45-59). The patches are stored in pouches

comprising polypropylene (col.12, lines 27-37). The patch further comprises adhesive to affix the patch to the skin (col.9, lines 55-57), and the matrix has polymer foam framework, the adhesive layer and polymer foam both read on the enclosure that is adhesive and prevents the organic material from contact subject's body as required by instant claims 1, 58 and 59. The patch comprises additives such as permeation enhancers including glycols, preservatives including alcohols, and plasticizers (col.13, lines 12-15, 49-52; col.14, lines 10-12). The capability of the left-handed molecule of causing beneficial effect as claimed by claim 5 and improving subject stamina as claimed by claim 42 are inherent function of the specific molecule. The limitation "wearable" as claimed by claim 59 is met by the reference because the according to the present disclosure, paragraphs 0034 and 0085, applicant defined "wearable object" as "dermal patches".

### ***Response to Arguments***

4. Applicant's arguments filed 05/19/2008 have been fully considered but they are not persuasive. Applicant traverses this rejection by arguing that the reference does not disclose enclosure that is adhesive and prevents organic material from direct contact with subject's body as instantly claimed by amended claim 1. Further '514 describes a transdermal pouch that releases its contents into, and makes direct contact with, the subject body, and the adhesive layer prevents excessive migration of the athletic supplement from the patch during storage, however, release the supplement once the patch is applied.

In response to this argument, applicant's attention is directed to the fact that it is well established that the claims are given the broadest interpretation during prosecution. The scope of the present claims is directed to product comprising specific organic materials in an enclosure so that the organic materials do not directly contact the skin. US '514 teaches product comprising the claimed organic materials and further teaches that the matrix including the organic materials has polymer foam framework (col.18, lines 10-14), and further comprises adhesive to affix the matrix to the skin (col.9, lines 55-57), and both of the foam framework and adhesive layer read on the enclosure that prevents the organic material from contact subject's body as required by instant claims 1, 58 and 59. Therefore, all the elements of claimed product are met by the references, and also the function required by the enclosure is met by the adhesive polymer and foam framework because both of them prevent the matrix comprising the organic materials from direct contact with the skin. The present claims do not exclude the release of the supplement from the patch. Further, the claims do not exclude contact with the subject body, only direct contact, and the reference teaches the adhesive layer as well as the foam framework that both prevent the direct contact with the subject's body. Therefore, all the limitation of the claims are met by US '514.

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over US '514 in view of US 5,651,973 ('973).

The teachings of US '514 are discussed in section 3 as set forth in this office action.

However, US '514 does not teach the patch is embodied in a bracelet as claimed by claim 26.

US '973 teaches transdermal patch that is attached to the back of suitable article such as wrist band or bracelet in order to eliminate the contact between irritating elements in the patch and the skin (col.11, lines 20-25).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide patch comprising plurality of amino acids including hydroxyproline and L-carnitine as disclosed by US '514, and attach the patch to a bracelet as disclosed by US '973, motivated by the teaching of US '973 that when the patch is attached to a bracelet it eliminates skin irritation, with reasonable expectation of having patch comprising amino acids and attached to a bracelet to effectively deliver amino acids to the wearer without irritating the skin.

7. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over US '514 in view of 6,558,695 ('695).

The teachings of US '514 are discussed in section 3 as set forth in this office action.

Although US '514 teaches additives, however, US '514 does not teach the specific additives as claimed by claim 34.

US '695 teaches transdermal patch comprising glycerin because it acts as irritation mitigating agent and eliminates the possibility of skin irritation (abstract; col.15, lines 14-20).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide patch comprising amino acids including hydroxyproline, L-carnitine, and additives as disclosed by US '514, and replace the additives with glycerin, or further add glycerin to the additives as disclosed by US '695, motivated by the teaching of US '695 that glycerin acts as irritation mitigating agent and eliminates the possibility of skin irritation, with reasonable expectation of having patch comprising amino acids and glycerin to effectively deliver amino acids to the wearer without irritating the skin.

### ***Response to Arguments***

8. Applicant's arguments filed 05/19/2007 have been fully considered but they are not persuasive. Applicant traverses the USC 103 rejections by arguing that the cited references, alone or in combination with one another, do not teach or suggest all the features of the claimed invention because both the '973 and the '695 describe transdermal delivery systems, these patents do not cure the defects of the '514 patent with regard to claim 1. The combination of the references does not teach all the features of claims 26 and 34.

In response to applicant's argument that the US '973 and US '695 are directed to transdermal patches, it is noted that the present claims are not directed to any specific devices, and the claims are directed to the generic limitation "apparatus" that encompasses transdermal devices. Applicant himself disclosed in paragraphs 0034 and 0085 of the present specification that "wearable objects" include "dermal patches". Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Additionally, US '973 is relied upon for the solely teachings of bracelet been used to provide active materials to subject, and US '695 is relied upon for the solely teaching of glycerin can be provided as additive to the organic materials delivered to subject. It has been held that "When a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraida v. AG Pro, Inc.*, 425 U.S. 273,282 (1976)). "When the question is whether a patent claiming the combination of elements of prior art is obvious," the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions."

A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been *prima facie* obvious within the meaning of 35 U.S.C. 103 (a).

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 2002/0072501 teaches L-carnitine to increase energy.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Art Unit: 1611

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/Isis A Ghali/  
Primary Examiner, Art Unit 1611

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